UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/520,760	03/07/2000	Krishan L. Taneja	BP9806US-CP1	9118

23544 7590 04/09/2002

BRIAN D. GILDEA
APPLIED BIOSYSTEMS
15 DEANGELO DRIVE
BEDFORD, MA 01730

EXAMINER
SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/09/2002 //

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/520,760	Taneja
Examiner	**Art Unit**
Jehanne Souaya	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 10, 2002*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☑ Claim(s) 1-2, 10-12, 29, 31, 33-34, 38-40, 45, 47, 49-50, 54-56, 64-66, 78-81 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☑ Claims 1-2, 10-12, 29, 31, 33-34, 38-40, 45, 47, 49-50, 54-56, 64-66, 78-81 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Applicant's arguments regarding the previous restriction requirement have been thoroughly reviewed as have each individual pending claim. In an effort not to unfairly limit applicant to a single chromosome, the restriction requirement has been rewritten (in particular, note groups XIV and XV), and the reasoning behind the requirement has been addressed in both the new restriction requirement as well as the response to arguments.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-2, 39-40, 54-56, and 64-66, drawn to non nucleic acid probes having nucleobase sequences directed to human chromosome X and to methods and kits for detecting, identifying, or quantitating human chromosome X in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

   II. Claims 1-2, 39-40, 54-56, and 64-66, drawn to non nucleic acid probes having nucleobase sequences directed to human chromosome Y and to methods and kits for detecting, identifying, or quantitating human chromosome Y in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

   III. Claims 1-2, 39-40, 54-56, and 64-66, drawn to non nucleic acid probes having nucleobase sequences directed to human chromosome 1 and to methods and kits for detecting, identifying, or quantitating human chromosome 1 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

IV. Claims 1-2, 39-40, 54-56, and 64-66, drawn to non nucleic acid probes having nucleobase sequences directed to human chromosome 2 and to methods and kits for detecting, identifying, or quantitating human chromosome 2 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

V. Claims 1-2, 29, 39-40, 45, 54-56, and 64-66, drawn to non nucleic acid probes having nucleobase sequences directed to human chromosome 3 and to methods and kits for detecting, identifying, or quantitating human chromosome 3 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

VI. Claims 1-2, 39-40, 54-56, and 64-66, drawn to non nucleic acid probes having nucleobase sequences directed to human chromosome 6 and to methods and kits for detecting, identifying, or quantitating human chromosome 6 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

VII. Claims 1-2, 31, 39-40, 47, 54-56, and 64-66, drawn to non nucleic acid probes having nucleobase sequences directed to human chromosome 8 and to methods and kits for detecting, identifying, or quantitating human chromosome 8 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

VIII. Claims 1-2, 39-40, 54-56, and 64-66, drawn to non nucleic acid probes having nucleobase sequences directed to human chromosome 10 and to methods and kits for detecting, identifying, or quantitating human chromosome 10 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

IX. Claims 1-2, 33, 39-40, 49, 54-56, and 64-66, drawn to non nucleic acid probes having nucleobase sequences directed to human chromosome 11 and to methods and kits for detecting, identifying, or quantitating human chromosome 11 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

X. Claims 1-2, 34, 39-40, 50, 54-56, and 64-66, drawn to non nucleic acid probes containing nucleobase sequences directed to human chromosome 12 and to methods and kits for detecting, identifying, or quantitating human chromosome 12 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

XI. Claims 1-2, 39-40, 54-56, and 64-66, drawn to non nucleic acid probes having nucleobase sequences directed to human chromosome 16 and to methods and kits for detecting, identifying, or quantitating human chromosome 16 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

XII. Claims 1-2, 39-40, 54-56, and 64-66, drawn to non nucleic acid probes having nucleobase sequences directed to human chromosome 17 and to methods and kits for detecting, identifying, or quantitating human chromosome 17 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

XIII. Claims 1-2, 39-40, 54-56, and 64-66, drawn to non nucleic acid probes having nucleobase sequences directed to human chromosome 18 and to methods and kits for detecting, identifying, or quantitating human chromosome 18 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

XIV. Claims 10-12, drawn to a non nucleic acid probe set having nucleobase sequences directed to detecting human chromosomes X, Y, 1, 2, 3, 6, 8, 10, 12, 16, 17, and 18, classified in class 536, subclass 23.1

XV. Claims 78-81, drawn to methods of detecting two or more human chromosomes X, Y, 1-3, 6, 8, 10, 12, 16-18 using non nucleic acid probes having nucleobase sequences, classified in class 435, subclass 6. (This group is subject to further restriction, see section 2 below).

2. The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I-XIII and XV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, each subcombination can be used to detect a single patentably distinct chromosome, or set of chromosomes. A nucleobase containing probe derived from chromosome X can be used to detect chromosome X and not chromosome 1. See MPEP § 806.05(d). The probes having nucleobase containing portions derived from chromosome X are structurally and functionally distinct from those derived from chromosome 1. Each chromosome is made up of different nucleic acid sequences that are patentably distinct from each other and require different nucleobase regions for their identification or detection. If applicant elects group XV, applicant should indicate which specific chromosomes are to be detected in the method. A method of detecting chromosomes X and Y is separately usable than a method of detecting chromosome 1 and 2 and does not require the nucleobase containing probes

directed to chromosomes 1 and 2, therefore a method of detecting chromosome X and Y is patentably distinct from a method of detecting chromosome 1 and 2.

3. The inventions of groups I-XIII, XV and XIV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed for the following reasons. The particulars of the subcombination, for example chromosome X, appear to be the nucleobase containing portions of the probes. A probe containing a nucleobase portion derived from chromosome X will not detect chromosome Y. Further, the combination drawn to a method or probe set for detecting chromosomes X, Y, 1, 2, 3, 6, 8, 11, 12, 16, 17, and 18 does not require a non nucleic acid probe having the specific nucleobase sequence of SEQ ID NO: 1. The subcombination has separate utility in other combinations. For example, the subcombination of probes for chromosome X have may have utility for sex determination when used in a combination of probes for chromosomes X and chromosome Y, whereas the subcombination of probes for chromosome X has utility for detecting abnormalities of specific chromosomes X, 1, and 2 when used in a combination of probes for chromosomes X, 1, and 2.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, for example, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Response to Arguments

6. Applicant's arguments have been thoroughly reviewed but were not found persuasive with regard to the following. Applicant traverses that the claims are generic in nature, and for example regarding claims 1 and 2, the claims are directed to a non-nucleic acid probe wherein the exact chemical composition of the probe is defined in Markush language and that the claims are not directed to a particular nucleobase sequence. Firstly, the examiner understands that the chemical structure of the claimed probes are not directed to *only* nucleic acid containing portions. Secondly, the examiner maintains that the claims are in improper Markush language as the nucleobase containing portions of the probes, at least those directed to a specific region of a specific chromosome, appear to be patentably distinct for the reasons made of record above and for the reasons set forth below. Further, the specification teaches that the probing nucleobase sequence is the sequence recognition portion of the construct (see p. 19, lines 26-27) and that each nucleobase portion was derived from specific regions for each specific chromosome (see pp 53-54, "Design of Chromosome Specific Probes"). Thirdly, the assertion that the claims are

not directed to a particular nucleobase sequence is not understood as the only distinguishing structural feature that is characteristic for each probe, set forth in the claim, is a *particular* nucleobase sequence. The specification acknowledges that PNA sequences, which are encompassed by the language "non nucleic acid probes" in the instantly claimed invention, were known in the art at the time of applicant's invention, as were other nucleobase containing constructs. Therefore, the only distinguishing structural feature of the probes in the presently claimed invention over generic PNA sequences, for example, are the specific nucleobase containing portions.

Further, applicants arguments are not understood because it appears that applicant is arguing that the probes are equivalent in that the function of the probe is not dependent on the nucleobase containing portion, whereas the specification teaches that the probing nucleobase sequence is the sequence recognition portion of the construct (see p. 19, lines 26-27) [which is presumably how one detects a specific chromosome] and that each nucleobase portion was derived from separate chromosomes (see pp 53-54, "Design of Chromosome Specific Probes"). The examiner takes the position that from the teachings in the specification, a probe containing a nucleobase containing portion specific to chromosome X will not be able to detect chromosome Y, it's function is to detect chromosome X. Thus, as chromosomes X and Y are different in structure and function, and are therefore patentably distinct, methods and probes to detect each chromosome are patentably distinct. The same argument is directed to the different chromosomes in the claims. Each set of probes for a specific chromosome appears to be directed

to a specific region of that chromosome, therefore, the inventions have been grouped by chromosome where the claims are only directed to detecting one or more chromosomes. Applicant can claim a specific method or probe set for detecting two, three, etc chromosomes. If this is applicants wish, the claims should be directed to a single specific combination of probes for specific chromosomes. A method or probe set for detecting chromosomes X and Y are patentably distinct from a probe set for detecting chromosomes 1 and 2 for example, because the former probe set can be used for sex determination, whereas the latter probe set can be used to detect abnormalities in chromosomes 1 and/or 2. As presently written, the claims are directed to "one or more" probes, which encompasses a single probe for a single chromosome. Claims 10-12 have been grouped separately if applicant wishes to claim a method and probe set containing all the probes or a probe set that contains at least specific probes for each chromosome, it is noted however, that presently, claim 10 is not directed to any specific probes and that claims 11 and 12 appear indefinite as they do not further limit claim 10 because they recite "one or more" whereas claim 10 specifies a minimum of 13 probes. If this is applicant's wish, applicant should amend the claims to specify a set containing all 118 probes and is requested to suggest a sequence for examination, to help alleviate the burden of searching, for example, all 118 probes (if all 118 are claimed, not "one or more" as claims 11 and 12 presently recite). For example, if the non nucleic acid probe having a probing nucleobase sequence of SEQ ID NO 1 is found allowable over the prior art, then any probe set containing a non nucleic acid probe having a

probing nucleobase sequence of SEQ ID NO 1 in addition to other probes would be allowable over the prior art.

With regard to applicants confusion with regard to the previous office action being a restriction or election of species, the examiner apologizes for the confusing language in the previous action and is issuing the present action to help alleviate this confusion.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634

4/5/02